Esperion Therapeutics, Inc.
Form 10-Q
November 01, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-35986

Esperion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-1870780**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3891 Ranchero Drive, Suite 150

Ann Arbor, MI 48108

(Address of principal executive office) (Zip Code)

Registrant s telephone number, including area code:

(734) 887-3903

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
Emerging growth company o	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of October 31, 2018, there were 26,811,002 shares of the registrant s Common Stock, $0.001 par value per share, outstanding.

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Esperion Therapeutics, Inc.

Condensed Balance Sheets

(in thousands, except share data)

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 26,755	$ 34,468
Short-term investments	132,463	165,731
Prepaid clinical development costs	7,411	2,072
Other prepaid and current assets	1,581	1,653
Total current assets	168,210	203,924
Property and equipment, net	583	435
Intangible assets	56	56
Long-term investments	5,181	73,420
Total assets	$ 174,030	$ 277,835
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 18,630	$ 20,375
Current portion of long-term debt		1,045
Accrued clinical development costs	20,030	10,506
Other accrued liabilities	3,625	1,218
Total current liabilities	42,285	33,144
Total liabilities	42,285	33,144
Commitments and contingencies (Note 5)		
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized and no shares issued or outstanding as of September 30, 2018 and December 31, 2017		
Common stock, $0.001 par value; 120,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 26,804,300 shares issued and outstanding at September 30, 2018 and 26,304,669 shares issued and outstanding at December 31, 2017	27	26
Additional paid-in capital	670,340	641,801
Accumulated other comprehensive loss	(560)	(845)
Accumulated deficit	(538,062)	(396,291)
Total stockholders equity	131,745	244,691
Total liabilities and stockholders equity	$ 174,030	$ 277,835

See accompanying notes to the condensed financial statements.

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Esperion Therapeutics, Inc.

Condensed Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 41,551	$ 40,056	$ 122,015	$ 114,164
General and administrative	9,011	5,681	21,921	16,122
Total operating expenses	50,562	45,737	143,936	130,286
Loss from operations	(50,562)	(45,737)	(143,936)	(130,286)
Other income, net	651	518	2,165	1,189
Net loss	$ (49,911)	$ (45,219)	$ (141,771)	$ (129,097)
Net loss per common share (basic and diluted)	$ (1.86)	$ (1.86)	$ (5.30)	$ (5.57)
Weighted-average shares outstanding (basic and diluted)	26,804,026	24,311,844	26,732,733	23,161,847
Other comprehensive loss:				
Unrealized gain (loss) on investments	$ 216	$ (112)	$ 285	$ (179)
Total comprehensive loss	$ (49,695)	$ (45,331)	$ (141,486)	$ (129,276)

See accompanying notes to the condensed financial statements.

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Esperion Therapeutics, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2018	**2017**
Operating activities		
Net loss	$ (141,771)	$ (129,097)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	191	196
Amortization of premiums and discounts on investments	(134)	314
Stock-based compensation expense	17,139	14,071
Changes in assets and liabilities:		
Prepaids and other assets	(5,267)	(1,458)
Accounts payable	(1,808)	14,906
Other accrued liabilities	11,704	4,640
Net cash used in operating activities	(119,946)	(96,428)
Investing activities		
Purchases of investments	(25,481)	(212,973)
Proceeds from sales/maturities of investments	127,408	128,740
Purchase of property and equipment	(46)	(19)
Net cash provided by (used in) investing activities	101,881	(84,252)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs		164,079
Proceeds from exercise of common stock options	11,401	732
Payments on long-term debt	(1,049)	(1,272)
Net cash provided by financing activities	10,352	163,539
Net decrease in cash and cash equivalents	(7,713)	(17,141)
Cash and cash equivalents at beginning of period	34,468	38,165
Cash and cash equivalents at end of period	$ 26,755	$ 21,024
Supplemental disclosure of cash flow information:		
Purchase of property and equipment not yet paid	$ 293	$
Offering costs not yet paid	$	$ 111

See accompanying notes to the condensed financial statements.

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Esperion Therapeutics, Inc.

Notes to the Condensed Financial Statements

(unaudited)

1. The Company and Basis of Presentation

The Company is the Lipid Management Company, a late-stage pharmaceutical company focused on developing and commercializing complementary, convenient, cost-effective, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C). Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease (CVD); the leading cause of death around the world. Bempedoic acid and the Company s lead product candidate, the bempedoic acid / ezetimibe combination pill, are targeted therapies that have been shown to significantly lower elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies.

The clinical development program for the bempedoic acid / ezetimibe combination pill consisted of a single pivotal Phase 3 clinical study (1002FDC-053) in patients with hypercholesterolemia and with atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH), including high CVD risk primary prevention patients, whose LDL-C is not adequately controlled despite receiving maximally tolerated lipid-modifying background therapy. 1002FDC-053 initiated in November 2017, fully enrolled 382 patients in March 2018, and the Company reported top-line results in August 2018.

The global pivotal Phase 3 clinical development program for bempedoic acid, consisting of four clinical studies, is complete with 3,621 high CVD risk patients with hypercholesterolemia and ASCVD and/or HeFH, or who are high CVD risk primary prevention, on optimized background lipid-modifying therapy and with elevated levels of LDL-C. These patients are on two distinct types of background lipid-modifying therapy: 1) patients on their maximally tolerated statin therapy, and 2) patients who are only able to tolerate less than the lowest approved daily starting dose of a statin, and can be considered stain intolerant. In March 2018, the Company reported top-line results from the first of the Phase 3 studies, Study 4 (1002-048). In May 2018, the Company reported top-line results from the 52-week long-term safety study, Study 1 (1002-040), and from Study 3 (1002-046). In October 2018, the Company reported top-line results from Study 2 (1002-047).

The Company intends to use positive results from the Phase 3 bempedoic acid / ezetimibe combination pill and bempedoic acid programs with a total of 4,003 patients to support global regulatory submissions for tandem LDL-C lowering indications in the U.S. no later than the first quarter of 2019 and in Europe no later than the second quarter of 2019.

The Company is also conducting a global cardiovascular outcomes trial (CVOT) known as **C**holest**e**rol **L**owering v**i**a B**E**mpedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes, for bempedoic acid in 12,604 patients with hypercholesterolemia and high CVD risk and who can be considered statin intolerant. The Company initiated the CLEAR Outcomes CVOT in December 2016 and expects the study to be fully enrolled in 2019, and intends to use positive results from this CVOT to support submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

The Company s primary activities since incorporation have been conducting research and development activities, including nonclinical, preclinical and clinical testing, performing business and financial planning, recruiting personnel, and raising capital. Accordingly, the Company has not commenced principal operations and is subject to risks and uncertainties which include the need to research, develop, and clinically test potential therapeutic products; obtain regulatory approvals for its products and commercialize them, if approved; expand its management and scientific staff; and finance its operations with an ultimate goal of achieving profitable operations.

The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future. Management plans to continue to fund operations through public or private equity or debt financings or through other sources, which may include collaborations with third parties. If adequate funds are not available, the Company may not be able to continue the development of its current or future product candidates, or to commercialize its current or future product candidates, if approved.

Basis of Presentation

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP). In the opinion of management, the Company has made all adjustments, which include only normal recurring adjustments necessary for a fair statement of the

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Company s financial position and results of operations for the interim periods presented. Certain prior year amounts have been reclassified to conform with current year presentation. Certain information and disclosures normally included in the annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2017, and the notes thereto, which are included in the Company s Annual Report on Form 10-K for the year ended December 31, 2017. The results of operations for the interim periods are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

2. Summary of Significant Accounting Policies

In January 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-01 which includes provisions to accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. The updated guidance requires equity investments with determinable fair values to be measured at fair value with changes in fair value recognized in income. Equity investments without determinable fair values are to be measured at cost, less any impairment determined to be other than temporary. The Company adopted ASU 2016-01 effective January 1, 2018. Prospectively, unrealized gains or losses from equity investments with readily determinable fair values will be reflected in earnings through Other income, net on the statement of operations and any equity investments owned by the Company without readily determinable fair values will be measured at cost, less any impairment determined to be other than temporary. The adoption of the ASU did not have a material impact to the Company s balance sheets, statements of operations or statements of cash flows.

In May 2017, the FASB issued ASU 2017-09 which includes provisions to clarify when to account for a change to terms or conditions of a share-based payment award as a modification. Under the updated guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. The Company adopted ASU 2017-09 effective January 1, 2018. The adoption of the ASU did not have a material impact to the Company s balance sheets, statements of operations or statements of cash flows.

In August 2018, the FASB issued ASU 2018-15 which includes provisions to clarify customer s accounting for implementation costs incurred in a cloud computing arrangement. Under the updated guidance, a customer in a cloud computing arrangement that is a service contract should follow the internal-use software guidance to determine how to account for costs incurred in implementation. The updated guidance also requires certain classification on the balance sheets, statements of operations and statements of cash flows as well as additional quantitative and qualitative disclosures. The standard is effective for public companies for fiscal years beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted and entities can choose to adopt the new guidance prospectively or retrospectively. The Company does not believe the adoption of this standard to have a material impact to the Company s balance sheets, statements of operations or statements of cash flows.

There have been no other material changes to the significant accounting policies previously disclosed in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

3. Debt

In June 2014, the Company entered into a loan and security agreement (the Credit Facility) with Oxford Finance LLC which provided for initial borrowings of $5.0 million under the term loan (the Term A Loan). On June 30, 2014, the Company received proceeds of $5.0 million from the issuance of secured promissory notes under the Term A Loan. The secured promissory notes issued under the Credit Facility bear interest at an annual rate of 6.40% and were due on July 1, 2018. A final payment equal to 8.0% of the Term A Loan was due upon the earlier of the maturity date or prepayment of the term loan. The Company recognized the final payment as interest expense using the effective interest method over the life of the Credit Facility. The Term A Loan was fully repaid in July 2018.

4. Warrants

In connection with the Credit Facility entered into in June 2014, the Company issued a warrant to purchase 8,230 shares of common stock at an exercise price of $15.19. The warrant will terminate on the earlier of June 30, 2019, and the closing of a merger or consolidation transaction in which the Company is not the surviving entity. The warrant was recorded at fair value of $0.1 million to additional-paid-in-capital in accordance with ASC 815-10 based upon the allocation of the debt proceeds.

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Upon the closing of the Company s Initial Public Offering, all warrants exercisable for 1,940,000 shares of Series A preferred stock, at an exercise price of $1.00 per share (unadjusted for stock splits), were automatically converted into warrants exercisable for 277,690 shares of common stock, at an exercise price of $6.99 per share. During the nine months ended September 30, 2018, the remaining 177,123 warrants were net exercised for 159,944 shares of the Company s common stock. During the year ended December 31, 2017, 71,237 warrants were net exercised for 62,525 shares of the Company s common stock.

As of September 30, 2018, the Company had warrants outstanding that were exercisable for a total of 8,230 shares of common stock at a weighted-average exercise price of $15.19 per share.

5. Commitments and Contingencies

On January 12, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against the Company and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that the Company and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving the Company s lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015 and September 28, 2015, as well as attorneys fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, the Company filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted the Company s motion to dismiss with prejudice and entered judgment in the Company s favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment. In May 2017, the court denied the plaintiff s motion to alter or amend the judgment. On June 19, 2017, the plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court s dismissal and remanded for further proceedings. On October 11, 2018, the Company filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit Court of Appeals directed plaintiffs to respond to that petition. The Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

On May 7, 2018, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, captioned Kevin Bailey v. Esperion Therapeutics, Inc., et al. (No. 18-cv-11438). An amended complaint was filed on October 22, 2018, against the Company and certain directors and officers. The amended complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 based on allegedly making false and misleading statements about the facts and circumstances surrounding the Phase 3 trial results for bempedoic acid that the Company announced on May 2, 2018. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between February 22, 2017, and May 22, 2018, as well as attorneys fees and costs. The Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

On July 6, 2018, the Company entered into the first amendment of the lease for the Company s principal executive office in Ann Arbor, Michigan. The amended lease is to increase the current 7,941 rentable square feet of office space by 11,471 rentable square feet, together with the right to use common areas and facilities in common with the landlord and other tenants. The term of the lease commences with respect to all of the space in the leased premises on the later to occur of (i) the date upon which landlord delivers the premises to the Company under the terms of the lease with the delivery conditions set forth in the lease satisfied and (ii) November 1, 2018 (the Lease Commencement Date). The term of the lease shall end 60 months after the Lease Commencement Date. Under the terms of the lease, following the first month (during which the base rent is $0) and the second month (during which the base rent is $15,990), the base rent, subject to certain adjustments, for the leased premises will start at approximately $19,412 per month, plus certain operating expenses and taxes, and shall increase on an annual basis and/or

as otherwise provided in the lease agreement. In addition, on May 14, 2018, the Company provided notice of early lease termination for its second Ann Arbor lease of 5,500 square feet to end its tenancy effective November 15, 2018.

There have been no other material changes to the Company s contractual obligations and commitments and contingencies outside the ordinary course of business from those previously disclosed in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

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6. Investments

The following table summarizes the Company s cash equivalents and investments:

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 22,071	$	$	$ 22,071
Short-term investments:				
Certificates of deposit	6,749		(13)	6,736
U.S. treasury notes	57,401		(248)	57,153
U.S. government agency securities	68,864		(290)	68,574
Long-term investments:				
Certificates of deposit	245		(2)	243
U.S. treasury notes	4,945		(7)	4,938
Total	$ 160,275	$	$ (560)	$ 159,715

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 27,302	$	$	$ 27,302
U.S. treasury notes	2,999			2,999
Short-term investments:				
Certificates of deposit	12,429	1	(13)	12,417
U.S treasury notes	97,537		(225)	97,312
U.S. government agency securities	56,143		(141)	56,002
Long-term investments:				
Certificates of deposit	3,863		(10)	3,853
U.S. treasury notes	27,983		(209)	27,774
U.S. government agency securities	42,041		(248)	41,793
Total	$ 270,297	$ 1	$ (846)	$ 269,452

At September 30, 2018, remaining contractual maturities of investments classified as current on the balance sheets were less than 12 months and remaining contractual maturities of investments classified as long-term were less than two years.

During the three and nine months ended September 30, 2018, other income, net in the statements of operations includes interest income on investments of $0.6 million and $2.1 million, and income for the accretion of premiums and discounts on investments of less than $0.1 million and $0.1 million, respectively. During the three and nine months ended September 30, 2017, other income, net in the statements of operations includes interest income on available-for-sale investments of $0.7 million and $1.7 million, and expense for the amortization of premiums and discounts on investments of less than $0.1 million and $0.3 million, respectively.

There were no unrealized gains or losses on investments reclassified from accumulated other comprehensive loss to other income in the statements of operations during the three and nine months ended September 30, 2018 and 2017.

7. Fair Value Measurements

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are defined on a three level hierarchy:

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Level 1 inputs: Quoted prices for identical assets or liabilities in active markets;

Level 2 inputs: Observable inputs other than Level 1 prices, such as quoted market prices for similar assets or liabilities or other inputs that are observable or can be corroborated by market data; and

Level 3 inputs: Unobservable inputs that are supported by little or no market activity and require the reporting entity to develop assumptions that market participants would use when pricing the asset or liability.

The following table presents the Company s financial assets and liabilities that have been measured at fair value on a recurring basis:

Description	Total	Level 1	Level 2	Level 3
		(in thousands)		
September 30, 2018				
Assets:				
Money market funds	$ 22,071	$ 22,071	$	$
Investments:				
Certificates of deposit	6,979	6,979		
U.S. treasury notes	62,091	62,091		
U.S. government agency securities	68,574		68,574	
Total assets at fair value	$ 159,715	$ 91,141	$ 68,574	$
December 31, 2017				
Assets:				
Money market funds	$ 27,302	$ 27,302	$	$
Available-for-sale securities:				
Certificates of deposit	16,270	16,270		
U.S. treasury notes	128,085	128,085		
U.S. government agency securities	97,795		97,795	
Total assets at fair value	$ 269,452	$ 171,657	$ 97,795	$

There were no transfers between Levels 1, 2 or 3 during the three and nine months ended September 30, 2018 and 2017.

8. Stock Compensation

2017 Inducement Equity Plan

In May 2017, the Company s board of directors approved the 2017 Inducement Equity Plan (the 2017 Plan). The number of shares of common stock available for awards under the 2017 Plan was set to 750,000, with any shares of common stock that are forfeited, cancelled, held back upon the exercise or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of common stock, or otherwise terminated (other than by exercise) under the 2017 Plan added back to the shares of common stock available for issuance under the 2017 Plan.

2013 Stock Option and Incentive Plan

In May 2015, the Company s stockholders approved the amended and restated 2013 Stock Option and Incentive Plan (as amended, the 2013 Plan). The number of shares of common stock available for awards under the 2013 Plan was set to 2,975,000 shares, plus (i) shares of common stock that are forfeited, cancelled, held back upon the exercise or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of common stock or otherwise terminated (other than by exercise) under the 2013 Plan and the Company s 2008 Incentive Stock Option and Restricted Stock Plan are added back to the shares of common stock available for issuance under the 2013 Plan, and (ii) on January 1, 2016, and each January 1, thereafter, the number of shares of common stock reserved and available for issuance under the 2013 Plan will be cumulatively increased by 2.5% of the number of shares of common stock outstanding on the immediately preceding December 31, or such lesser number of shares of common stock determined by the compensation committee.

The 2017 Plan provides for the granting of stock options, stock appreciation rights, restricted stock awards, restricted stock units (RSUs), unrestricted stock awards and dividend equivalent rights. The 2013 Plan provides for the

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granting of stock options, stock appreciation rights, restricted stock awards, RSUs, unrestricted stock awards, cash-based awards, performance share awards and dividend equivalent rights. The Company incurs stock-based compensation expense related to stock options and RSUs. The fair value of RSUs is determined by the closing market price of the Company s common stock on the date of grant. The fair value of stock options is calculated using a Black-Scholes option pricing model. The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, Compensation Stock Compensation. Accordingly, compensation costs related to equity instruments granted are recognized over the requisite service periods of the awards on a straight-line basis at the grant-date fair value. In accordance with the adoption of ASU 2016-09, the Company accounts for forfeitures as they occur.

The following table summarizes the activity relating to the Company s options to purchase common stock for the nine months ended September 30, 2018:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	4,159,151	$ 28.13	7.39	$ 165,385
Granted	1,096,827	$ 60.30		
Forfeited or expired	(362,415)	$ 40.57		
Exercised	(336,875)	$ 33.84		
Outstanding at September 30, 2018	4,556,688	$ 34.46	7.23	$ 78,758

The following table summarizes information about the Company s stock option plan as of September 30, 2018:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Vested and expected to vest at September 30, 2018	4,556,688	$ 34.46	7.23	$ 78,758
Exercisable at September 30, 2018	2,738,990	$ 28.19	6.18	$ 59,605

During the three and nine months ended September 30, 2018, the Company recognized $5.3 million and $16.6 million, respectively, of stock-based compensation expense related to stock options. During the three and nine months ended September 30, 2017, the Company recognized $4.9 million and $13.8 million, respectively, of stock-based compensation expense related to stock options. As of September 30, 2018, there was $46.3 million of unrecognized stock-based compensation expense related to unvested options, which will be recognized over a weighted-average period of 2.9 years.

The following table summarizes the activity relating to the Company s RSUs for the nine months ended September 30, 2018:

	Number of RSUs	Weighted-Average Fair Value Per Share

Outstanding and unvested at December 31, 2017	10,003	$	57.54
Granted	34,000	$	67.94
Forfeited or expired	(4,691)	$	57.54
Vested	(2,812)	$	57.54
Outstanding and unvested at September 30, 2018	36,500	$	67.23

During the three and nine months ended September 30, 2018, the Company recognized $0.2 million and $0.5 million, respectively, of stock-based compensation expense related to RSUs. During the three and nine months ended September 30, 2017, the Company recognized $0.1 million and $0.3 million, respectively, of stock-based compensation expense recognized related to RSUs. As of September 30, 2018, there was $2.1 million of unrecognized stock-based compensation expense related to unvested RSUs, which will be recognized over a weighted-average period of 3.3 years.

9. Income Taxes

There was no provision for income taxes for the three and nine months ended September 30, 2018 and 2017, because the Company has incurred operating losses since inception. At September 30, 2018, the Company concluded that it is

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not more likely than not that the Company will realize the benefit of its deferred tax assets due to its history of losses. Accordingly, a full valuation allowance has been applied against the net deferred tax assets.

10. Net Loss Per Common Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, warrants for common stock, stock options and unvested RSUs are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The shares outstanding at the end of the respective periods presented below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	September 30, 2018	December 31, 2017
Warrants for common stock	8,230	185,353
Common shares under option	4,556,688	4,159,151
Unvested RSUs	36,500	10,003
Total potential dilutive shares	4,601,418	4,354,507

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our annual report on Form 10-K for the fiscal year ended December 31, 2017.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are based on our management s belief and assumptions and on information currently available to management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events, including our clinical development plans, or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, including in relation to the clinical development of the bempedoic acid / ezetimibe combination pill and bempedoic acid to be materially different from any future results, performance or achievements, including in relation to the clinical development of the bempedoic acid / ezetimibe combination pill and bempedoic acid, expressed or implied by these forward-looking statements.

Forward-looking statements are often identified by the use of words such as, but not limited to, may, will, should, expects, intends, plans, anticipates, believes, estimates, predicts, potential, continue or the negative of these terms or other similar terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and that could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those referred to or discussed in or incorporated by reference into the section titled Risk Factors included in Item 1A of Part II of this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements in this report represent our views as of the date of this quarterly report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

Corporate Overview

We are the Lipid Management Company, a late-stage pharmaceutical company focused on developing and commercializing complementary, convenient, cost-effective, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol, or LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease, or CVD; the leading cause of death around the world. Bempedoic acid and our lead product candidate, the bempedoic acid / ezetimibe combination pill, are targeted therapies that have been shown to significantly lower elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies.

The clinical development program for the bempedoic acid / ezetimibe combination pill consisted of a single pivotal Phase 3 study (1002FDC-053) in patients with hypercholesterolemia and with atherosclerotic cardiovascular disease, or ASCVD, and/or heterozygous familial hypercholesterolemia, or HeFH, including high CVD risk primary prevention patients, whose LDL-C is not adequately controlled despite receiving maximally tolerated lipid-modifying background therapy. 1002FDC-053 initiated in November 2017, fully enrolled 382 patients in March 2018, and we reported top-line results in August 2018.

The global pivotal Phase 3 clinical development program for bempedoic acid, consisting of four clinical studies, is complete with 3,621 high CVD risk patients with hypercholesterolemia and ASCVD and/or HeFH, or who are high CVD risk primary prevention, on optimized background lipid-modifying therapy and with elevated levels of LDL-C. These patients are on two distinct types of background lipid-modifying therapy: 1) patients on their maximally tolerated statin therapy, and 2)

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patients who are only able to tolerate less than the lowest approved daily starting dose of a statin, and can be considered statin intolerant. In March 2018, we reported top-line results from the first of the Phase 3 studies, Study 4 (1002-048). In May 2018, we reported top-line results from the 52-week long-term safety study, Study 1 (1002-040), and from Study 3 (1002-046). In October 2018, we reported top-line results from Study 2 (1002-047).

We intend to use positive results from our Phase 3 bempedoic acid / ezetimibe combination pill and bempedoic acid programs with a total of 4,003 patients to support global regulatory submissions for tandem LDL-C lowering indications in the U.S. no later than the first quarter of 2019 and in Europe no later than the second quarter of 2019.

We are also conducting a global cardiovascular outcomes trial, or CVOT, known as **C**holesterol **L**owering via **BE**mpedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes, for bempedoic acid in 12,604 patients with hypercholesterolemia and high CVD risk and who can be considered statin intolerant. We initiated the CLEAR Outcomes CVOT in December 2016 and expect the study to be fully enrolled in 2019, and intend to use positive results from this CVOT to support submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

We were incorporated in Delaware in January 2008, and commenced our operations in April 2008. Since our inception, we have focused substantially all of our efforts and financial resources on developing the bempedoic acid / ezetimibe combination pill and bempedoic acid. We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock and the incurrence of indebtedness, and we have incurred losses in each year since our inception. We own the exclusive worldwide rights to bempedoic acid.

We do not have any products approved for sale. To date, we have not generated any revenue. We have never been profitable and our net losses were $49.9 million and $45.2 million for the three months ended September 30, 2018 and 2017, respectively, and were $141.8 million and $129.1 million for the nine months ended September 30, 2018 and 2017, respectively. Substantially all of our net losses resulted from costs incurred in connection with research and development programs, general and administrative costs associated with our operations. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, including, among others:

- completing the clinical development of bempedoic acid, including the completion of the global pivotal Phase 3 LDL-C lowering program and the CLEAR Outcomes CVOT;

- completing the clinical development activities for the bempedoic acid / ezetimibe combination pill;

- seeking regulatory approval for the bempedoic acid / ezetimibe combination pill and bempedoic acid;

- commercializing the bempedoic acid / ezetimibe combination pill and bempedoic acid, if approved; and

- operating as a public company.

Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or through other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy or continue operations. We will need to generate significant revenues to achieve profitability, and we may never do so.

Product Overview

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination pill is our lead, non-statin, orally available, once-daily, LDL-C lowering therapy. Inhibition of ATP citrate lyase, or ACL, by bempedoic acid reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Inhibition of Niemann-Pick C1-Like 1 by ezetimibe results in reduced absorption of cholesterol from the gastrointestinal tract, thereby reducing delivery of cholesterol to the liver, which in turn upregulates the LDL receptors. Phase 3 data demonstrated that this safe and well tolerated combination results in a 35 percent lowering of LDL-C when used with maximally tolerated statins, a 43 percent lowering of LDL-C when used as a monotherapy, and a 34 percent reduction in high sensitivity C-reactive protein, or hsCRP. The bempedoic acid / ezetimibe combination pill is being developed for patients at high CVD risk with hypercholesterolemia.

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With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ACL inhibitor that, similar to statins, reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Similar to statins, bempedoic acid also reduces hsCRP, a key marker of inflammation associated with cardiovascular disease. Completed Phase 2 and Phase 3 studies conducted in almost 4,800 patients, including approximately 3,100 patients treated with bempedoic acid, have produced an additional 20 percent LDL-C lowering when used with maximally tolerated statins, up to 30 percent LDL-C lowering as a monotherapy, 35 percent in combination with ezetimibe when used with maximally tolerated statins, and up to 48 percent LDL-C lowering in combination with ezetimibe as monotherapy. Bempedoic acid is being developed for patients at high CVD risk with hypercholesterolemia. We acquired the rights to bempedoic acid from Pfizer in 2008. We own the exclusive worldwide rights to bempedoic acid and we are not obligated to make any royalty or milestone payments to Pfizer.

During the nine months ended September 30, 2018, we incurred $90.1 million in expenses related to the four studies in our global pivotal Phase 3 LDL-C lowering program, our CLEAR Outcomes CVOT, our 1002FDC-053 study, our open-label extension study, our 1002FDC-058 study and our Phase 2 (1002-39) clinical study of bempedoic acid when added-on to an injectable proprotein convertase subtilisin/kexin type 9 inhibitor, or PCSK9i, therapy in patients with hypercholesterolemia.

During the nine months ended September 30, 2017, we incurred $85.9 million in expenses related to the four studies in our global pivotal Phase 3 LDL-C lowering program, our CLEAR Outcomes CVOT, our Phase 2 (1002-038) clinical study of the bempedoic acid / ezetimibe combination plus atorvastatin with bempedoic acid 180 mg, ezetimibe 10 mg and atorvastatin 20 mg in patients with hypercholesterolemia and our Phase 2 (1002-39) clinical study of bempedoic acid when added-on to a PCSK9i in patients with hypercholesterolemia.

Program Developments

On October 28, 2018, we announced the completion of the Phase 3 LDL-C lowering development program of bempedoic acid and positive cumulative results. The Phase 3 program included 3,621 high cardiovascular risk patients taking maximally tolerated statin, which could include no statin, who required additional LDL-C lowering. The program achieved its efficacy endpoints and other key measures at 12 weeks for bempedoic acid, including:

- On-treatment LDL-C lowering of an additional 18 percent to 31 percent (vs. placebo, $p<0.001$), and in the intent to treat analysis LDL-C lowering of an additional 17 percent to 28 percent ($p<0.001$).

- Reductions of 19 percent to 33 percent in hsCRP, an important marker of the underlying inflammation associated with cardiovascular disease.

- Reductions in hemoglobin A1c, or HbA1c, of 0.19% to 0.31% vs. placebo in patients with diabetes.

In the Phase 3 LDL-C lowering development program, adjudicated major adverse cardiovascular events, or MACE, in the bempedoic acid arm as compared to placebo were the following:

Adjudicated MACE Events in Bempedoic Acid Compared to Placebo

(Cumulative Phase 3 Study Data)

	% of Patients	
Major Adverse Cardiovascular Events (MACE)	**Bempedoic Acid N=2,424**	**Placebo N=1,197**
3-component MACE	1.9%	2.3%
4-component MACE	3.8%	4.2%
5-component MACE	4.0%	4.6%

In the Phase 3 program, bempedoic acid was observed to be safe and well-tolerated. The vast majority (>80%) of patients were studied for 52 weeks. Across the program there were no clinically relevant differences between the bempedoic acid and placebo treatment groups in the occurrence of adverse events, with summarized results as follows:

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Adverse Events in Treatment Groups

(Cumulative Phase 3 Study Data)

	% of Patients	
Treatment Emergent Adverse Events (AEs)	**Bempedoic Acid N=2,424**	**Placebo N=1,197**
Overview of AEs in All Patients (patient incidence)		
Any AE(s)	73%	73%
Serious AE(s)	14%	13%
Discontinuation due to AE(s)	11%	8%

	Bempedoic Acid N=2,424	**Placebo N=1,197**
Fatal Adverse Events Unrelated to Study Medication		
Cardiovascular death	0.4%	0.3%
Non-Cardiovascular death		
Neoplasms	0.2%	0.0%
Sepsis/septic shock	0.1%	0.1%
Other	0.1%	0.0%

Fatal adverse events were very low overall at 0.8% and 0.3%, respectively (compared to a 1.8% annual fatality rate for people 65-74 year olds according to the CDC).

- No fatal adverse events were determined by the independent study investigator to be related to study medication.

- The bempedoic acid arm included a case of gas poisoning and a case of pancreatitis resulting from a pancreatic pseudocyst.

Phase 3 Clinical Studies Completed in 2018

Study 2 Global pivotal Phase 3 long-term safety and tolerability study in patients with hypercholesterolemia on maximally tolerated background lipid-modifying therapy

On October 28, 2018, we announced the top-line results from the pivotal Phase 3 study, Study 2 (1002-047). The 52-week, global, pivotal, Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the efficacy and safety of bempedoic acid 180 mg/day versus placebo in high CVD risk patients with hypercholesterolemia with ASCVD and/or HeFH, whose LDL-C is inadequately controlled with current lipid-modifying therapies, and who are taking maximally tolerated statin therapy. The study was conducted at 93 sites in North America and Europe. A total of 779 patients were randomized 2:1 to receive bempedoic acid or placebo. The primary objective was to assess the 12-week

LDL-C lowering efficacy of patients treated with bempedoic versus placebo. Secondary objectives included evaluating the safety and tolerability of bempedoic acid versus placebo, the 24-week and 52-week LDL-C lowering efficacy of bempedoic acid versus placebo, and its effect on other risk markers after 12 weeks of treatment, including hsCRP. While analyses of the complete efficacy and safety results from Study 2 are ongoing, the top-line results are summarized as follows:

LDL-Cholesterol Percent Change from Baseline to Week 12 Endpoint (LDL-C On-Treatment Analysis)

Treatment Group	Number of Patients	LDL-C Baseline Mean (SD) mg/dL	LDL-C Week 12 Endpoint Mean (SD) mg/dL	Percent Change from Baseline LS Mean (SE)	P Value
Bempedoic Acid	476	119 (38)	97 (34)	16% (1.1)	<0.001
Placebo	245	122 (38)	122 (43)	+2% (1.4)	

LS = least squares; SD = standard deviation; SE = standard error; mITT population

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LDL-Cholesterol Percent Change from Baseline to Week 12 Endpoint (Intent to Treat Analysis)

Treatment Group	Number of Patients	LDL-C Baseline Mean (SD) mg/dL	LDL-C Week 12 Endpoint Mean (SD) mg/dL	Percent Change from Baseline LS Mean (SE)	P Value
Bempedoic Acid	522	119 (38)	98 (34)	15% (1.1)	<0.001
Placebo	257	122 (38)	123 (41)	+2% (1.4)	

LS = least squares; SD = standard deviation; SE = standard error; ITT population

Adverse Events and Discontinuations at 52 Weeks

Treatment Emergent Adverse Events (AEs)	% of Patients Bempedoic Acid N=522	Placebo N=257
Overview of AEs in All Patients		
Any AE(s)	70%	71%
Serious AE(s)	20%	19%
Discontinuation due to AE(s)	11%	9%

	Bempedoic Acid N=522	Placebo N=257
Fatal Adverse Events Unrelated to Study Medication		
Cardiovascular death	0.8%	0.8%
Non-Cardiovascular death		
Septic shock(1)	0.2%	0.0%
Gas poisoning(2)	0.2%	0.0%

(1)Patient died from septic shock that was a complication of planned abdominal surgery

(2)Death was reported verbatim as CO2 gas poisoning

hsCRP Nonparametric Analysis

Treatment Group	Number of Patients	Baseline Level (mg/L)	Percent Change from Baseline Median Change	P Value
Bempedoic Acid	467	1.6	-19%	.039
Placebo	240	1.9	-9%	

- Bempedoic acid was observed to be safe and well-tolerated over a 52-week period. There were no clinically relevant differences between bempedoic acid and the placebo groups in the occurrence of AEs, SAEs or discontinuations due to AEs.

- After twelve weeks of treatment with bempedoic acid, LDL-C levels were lowered by 18% ($p<0.001$), with a decrease of 16% from baseline for the patients treated with bempedoic acid and an increase of 2% for patients who received placebo.

- hsCRP, a marker of the underlying inflammation associated with CVD, was reduced by 19% ($p=.039$) for patients dosed with bempedoic acid after twelve weeks of therapy, versus a 9% decrease with placebo.

- Clinically significant reductions in total cholesterol, apoB and non-HDL-C were seen in the patients treated with bempedoic acid.

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1002FDC-053 Phase 3 efficacy and safety study of the bempedoic acid / ezetimibe combination pill in patients with hypercholesterolemia

On August 27, 2018, we announced the top-line results from the pivotal Phase 3 bempedoic acid / ezetimibe combination pill study (1002FDC-1003). The 12-week, pivotal Phase 3 randomized, double-blind, parallel group, multicenter study evaluated the efficacy and safety of bempedoic acid 180 mg / ezetimibe 10 mg combination pill compared to bempedoic acid 180 mg alone, ezetimibe 10 mg alone or placebo in high-risk patients with ASCVD and/or HeFH or with multiple risk factors for ASCVD being treated with maximally tolerated statins. The study was conducted at 78 sites in North America. A total of 382 patients were randomized 2:2:2:1 to receive bempedoic acid 180 mg / ezetimibe 10 mg combination pill, bempedoic acid 180 mg, ezetimibe 10mg or placebo. The co-primary objectives of the study were to assess LDL-C lowering efficacy in patients treated with the bempedoic acid / ezetimibe combination pill versus placebo, 180 mg of bempedoic acid and 10 mg of ezetimibe alone. The secondary objectives included assessments of hsCRP, non-HDL-C, total cholesterol, or TC, and apoB after 12 weeks of treatment as well as characterizing the safety and tolerability of the combination pill versus placebo alone, bempedoic acid alone, and ezetimibe alone. While analyses of the complete efficacy and safety results from 1002FDC-053 are ongoing, the top-line results are summarized as follows:

LDL-Cholesterol Percent Change from Baseline to Week 12 Endpoint (LDL-C On-Treatment Analysis)

Treatment Group	Number of Patients	LDL-C Baseline Mean (SD) mg/dL	LDL-C Week 12 Endpoint Mean (SD) mg/dL	Percent Change from Baseline LS Mean (SE)	P Value
Bempedoic Acid / Ezetimibe Combination Pill	97	152 (39)		35% (2.4)	<0.001*
Bempedoic Acid	95	146 (36)		20% (2.4)	
Ezetimibe	95	147 (39)		24% (2.1)	
Placebo	49	153 (42)		3% (3.4)	

*vs. placebo

LS = least squares; SD = standard deviation; SE = standard error; mITT population

LDL-Cholesterol Percent Change from Baseline to Week 12 Endpoint (Intent to Treat Analysis)

Treatment Group	Number of Patients	LDL-C Baseline Mean (SD) mg/dL	LDL-C Week 12 Endpoint Mean (SD) mg/dL	Percent Change from Baseline LS Mean (SE)	P Value
Bempedoic Acid / Ezetimibe Combination Pill	108	152 (39)		32% (2.5)	<0.001*
Bempedoic Acid	110	146 (36)		18% (2.3)	
Ezetimibe	109	147 (39)		21% (2.0)	

Placebo	55	153 (42)	3% (3.1)

*vs. placebo

LS = least squares; SD = standard deviation; SE = standard error; ITT population

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hsCRP Nonparametric Analysis

Treatment Group	Number of Patients	Baseline Level (mg/L)	Percent Change from Baseline Median Change	P Value
Bempedoic Acid / Ezetimibe Combination Pill	102	3.1	34%	<0.05*
Bempedoic Acid	101	3.0	-20%	
Ezetimibe	102	3.0	-9%	
Placebo	52	3.0	+4%	

*versus placebo and ezetimibe

- After 12 weeks of treatment with the bempedoic acid / ezetimibe combination pill, LDL-C levels were lowered by 35% (p<0.001) compared to 24% for patients who received ezetimibe, 20% for patients that received bempedoic acid, and 3% for patients that received placebo in the on-treatment analysis. The study met its primary endpoint of LDL-C lowering of 32% at 12 weeks in the intent to treat (ITT) analysis, with a 21% lowering for patients who received ezetimibe (p<0.001), 18% for patients who received bempedoic acid (p<0.001), and 3% for patients who received placebo (p<0.001).

- hsCRP, a marker of inflammation associated with CVD, was reduced by 34% (p<0.05 vs. placebo and ezetimibe) for patients dosed with the bempedoic acid / ezetimibe combination pill after twelve weeks of therapy, versus a 4% increase with placebo and reductions of 20% for bempedoic acid and 9% for ezetimibe.

- Clinically significant lowering of total cholesterol, apoB and non-HDL-C were seen in the patients treated with the bempedoic acid / ezetimibe combination pill and bempedoic acid.

- The bempedoic acid / ezetimibe combination pill and bempedoic acid were observed to be safe and well-tolerated in this study. There were no clinically relevant differences in the occurrence of SAEs and discontinuations due to AEs among the four patient groups.

Study 3 Global pivotal Phase 3 LDL-C lowering efficacy and safety study in patients with hypercholesterolemia not adequately controlled with current lipid-modifying therapy and considered statin intolerant

On May 23, 2018, we announced the top-line results from the pivotal Phase 3 study, Study 3 (1002-046). The 24-week, global, pivotal, Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the LDL-C lowering efficacy and safety of bempedoic acid 180 mg/day versus placebo added to background lipid-modifying therapy in patients with

hypercholesterolemia who are considered statin intolerant. The study was conducted at 67 sites in the U.S. and Canada. A total of 345 patients were randomized 2:1 to receive bempedoic acid or placebo. The primary efficacy objective was to assess the 12-week LDL-C lowering efficacy of bempedoic acid versus placebo. Secondary objectives included evaluating the 24-week LDL-C lowering efficacy of bempedoic acid versus placebo, the safety and tolerability of bempedoic acid versus placebo, and its effects on other risk markers after 12 weeks of treatment, including hsCRP. While analyses of the complete efficacy and safety results from Study 3 are ongoing, the top-line results are summarized as follows:

LDL-Cholesterol Percent Change from Baseline to Week 12 Endpoint (LDL-C On-Treatment Analysis)

Treatment Group	Number of Patients	LDL-C Baseline Mean (SD) mg/dL	LDL-C Week 12 Endpoint Mean (SD) mg/dL	Percent Change from Baseline LS Mean (SE)	P Value
Bempedoic Acid	204	158 (41)	116 (36)	26% (1.3)	<0.001
Placebo	101	157 (40)	153 (43)	2% (1.4)	

LS = least squares; SD = standard deviation; SE = standard error; mITT population

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LDL-Cholesterol Percent Change from Baseline to Week 12 Endpoint (Intent to Treat Analysis)

Treatment Group	Number of Patients	LDL-C Baseline Mean (SD) mg/dL	LDL-C Week 12 Endpoint Mean (SD) mg/dL	Percent Change from Baseline LS Mean (SE)	P Value
Bempedoic Acid	234	159 (40)	120 (38)	23% (1.3)	<0.001
Placebo	111	156 (39)	153 (42)	1% (1.4)	

LS = least squares; SD = standard deviation; SE = standard error; ITT population

hsCRP Nonparametric Analysis

Treatment Group	Number of Patients	Baseline Level (mg/L)	Percent Change from Baseline Median Change	P Value
Bempedoic Acid	231	2.9	25%	<0.001
Placebo	106	2.8	+3%	

- After 12 weeks on treatment with bempedoic acid, LDL-C levels were lowered by 26% (p<0.001) in patients on bempedoic acid who remained on treatment at both week 12 and week 24 (an absolute reduction of 43 mg/dL) and a decrease of 2% for patients who received placebo. The study met its primary endpoint with LDL-C lowering of 23% (p<0.001) at 12 weeks in the intent to treat (ITT) analysis (an absolute reduction of 39 mg/dL), and a decrease of 1% for patients who received placebo.

- hsCRP, a marker of inflammation associated with CVD, was reduced by 25% (p<0.001) for patients dosed with bempedoic acid after twelve weeks of therapy, versus a 3% increase with placebo.

- Clinically significant reductions in total cholesterol, apoB and non-HDL-C were seen in the patients treated with the bempedoic acid.

- Bempedoic acid was observed to be safe and well-tolerated. There were no clinically relevant differences in the occurrence of AEs and no differences in discontinuations due to muscle-related AEs between the bempedoic acid group compared to the placebo group. Muscle-related adverse events were lower in the bempedoic acid group than in the placebo group.

Study 1 Global pivotal Phase 3 long-term safety and tolerability study in patients with hypercholesterolemia on maximally tolerated background lipid-modifying therapy

On May 2, 2018, we announced the top-line results from the pivotal Phase 3 study, Study 1 (1002-040). The 52-week, global, pivotal, Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the long-term safety and tolerability of bempedoic acid 180 mg/day versus placebo in high-risk patients with ASCVD and/or HeFH whose LDL-C is inadequately controlled with current lipid-modifying therapies, including maximally tolerated statin therapy. The study was conducted at 117 sites in the U.S., Canada and Europe. A total of 2,230 patients were randomized 2:1 to receive bempedoic acid or placebo. The primary objective was to assess the long-term safety and tolerability of bempedoic acid versus placebo over 52 weeks. The secondary objective was to assess the 12-week LDL-C lowering efficacy of bempedoic acid versus placebo. Tertiary objectives were to assess the effect of bempedoic acid on other lipid parameters and risk markers, including hsCRP. Final results of the study were presented by Kausik K. Ray, MBChB, MD, MPhil of Imperial College London on August 25, 2018 at the European Society of Cardiology. The final results are summarized as follows:

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Adverse Events and Discontinuations at 52 Weeks

	% of Patients	
Treatment Emergent Adverse Events (AEs)	**Bempedoic Acid N=1,487**	**Placebo N=742**
Overview of AEs in All Patients (patient incidence)		
Any AE(s)	78.5%	78.7%
Serious AE(s)	14.5%	14.0%
Discontinuations due to AE(s)	10.9%	7.1%
Fatal Adverse Events Unrelated to Study Treatment	0.9%	0.3%

On-Treatment LDL-Cholesterol Percent Change from Baseline to Week 12 Endpoint

				Percent Change from Baseline	
Treatment Group	**Number of Patients**	**LDL-C Baseline Mean (SD) mg/dL**	**LDL-C Week 12 Endpoint Mean (SD) mg/dL**	**LS Mean (SE)**	**P Value**
Bempedoic Acid	1,335	104 (29)	83 (27)	18% (0.5)	<0.001
Placebo	695	102 (30)	103 (35)	+2% (0.9)	

LS = least squares; SD = standard deviation; SE = standard error; mITT population

hsCRP Nonparametric Analysis

			Percent Change from Baseline	
Treatment Group	**Number of Patients**	**Baseline Level (mg/L)**	**Median Change**	**P Value**
Bempedoic Acid	1,421	1.49	22%	<0.001
Placebo	724	1.51	+3%	

- Bempedoic acid was observed to be safe and well-tolerated over a 52-week period, the primary endpoint of the study. There were no clinically relevant differences between bempedoic acid and the placebo groups in the occurrence of AEs, SAEs or discontinuations due to muscle-related AEs.

- After twelve weeks of treatment with bempedoic acid, LDL-C levels were lowered by 20% ($p<0.001$), with a decrease of 18% from baseline for the patients treated with bempedoic acid and an increase of 2% for patients who received placebo. This was the key efficacy endpoint of the study.

- hsCRP, a marker of the underlying inflammation associated with CVD, was reduced by 22% (p<0.001) for patients dosed with bempedoic acid after twelve weeks of therapy, versus a 3% increase with placebo.

- Clinically significant reductions in total cholesterol, apoB and non-HDL-C were seen in the patients treated with bempedoic acid.

Study 4 Global pivotal Phase 3 LDL-C lowering efficacy and safety study in patients with hypercholesterolemia not adequately controlled with current lipid-modifying therapy, including ezetimibe, and patients considered statin intolerant

On March 7, 2018, we announced the top-line results from the pivotal Phase 3 study, Study 4 (1002-048). The 12-week, global, pivotal, Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the efficacy and safety of bempedoic acid 180 mg/day versus placebo as add-on therapy in patients with ASCVD, or at a high risk for ASCVD, who are inadequately treated with current lipid-modifying therapies, including ezetimibe and up to the lowest approved daily starting dose of a statin. The study was conducted at 90 sites in the U.S., Canada and Europe. A total of 269

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patients were randomized 2:1 to receive bempedoic acid or placebo. The primary objective was to assess the 12-week LDL-C-lowering efficacy of bempedoic acid versus placebo when added to ezetimibe and up to the lowest starting dose of a statin. Secondary objectives included evaluating the safety and tolerability of bempedoic acid versus placebo, and its effects on other risk markers, including hsCRP. Final results of the study were presented by Christie M. Ballantyne M.D. of Baylor College of Medicine on June 12, 2018 at the XVIIIth International Symposium on Atherosclerosis, and were published simultaneously in the journal *Atherosclerosis.* The final results are summarized as follows:

LDL-Cholesterol Percent Change from Baseline to Week 12 Endpoint

Treatment Group	Number of Patients	LDL-C Baseline Mean (SD) mg/dL	LDL-C Week 12 Endpoint Mean (SD) mg/dL	Percent Change from Baseline LS Mean (SE)	P Value
Bempedoic Acid	181	130 (31)	96 (17)	23% (2.0)	<0.001
Placebo	88	123 (27)	129 (27)	+5% (2.3)	

LS = least squares; SD = standard deviation; SE = standard error; mITT population

hsCRP Nonparametric Analysis

Treatment Group	Number of Patients	Baseline Level (mg/L)	Percent Change from Baseline Median Change	P Value
Bempedoic Acid	180	2.21	33%	<0.001
Placebo	88	2.26	+2%	

- After twelve weeks of treatment with bempedoic acid, the primary endpoint of the study, LDL-C levels were lowered by 28% (p<0.001), with a decrease of 23% from baseline for the patients treated with bempedoic acid and an increase of 5% for patients who received placebo.

- hsCRP, a marker of the underlying inflammation associated with CVD, was reduced by 33% (p<0.001) for patients dosed with bempedoic acid after twelve weeks of therapy, versus a 2% increase with placebo.

- Clinically significant reductions in total cholesterol, apoB and non-HDL-C were seen in the patients treated with the bempedoic acid / ezetimibe combination plus atorvastatin.

- Discontinuation rates for bempedoic acid were low and comparable to placebo. There were two patients out of 181 (1.1%) treated with bempedoic acid with increases (> 3x the upper limit of normal, repeated and confirmed) in

liver function tests. The cumulative number of patients treated with bempedoic acid in Phase 2 studies and Study 4 total 947. Of these, six patients (0.65%) had elevations in liver function tests. The rate of elevations in liver function teats is consistent with the rate observed in Phase 2 clinical trials and with all other previously approved oral LDL-C lowering therapies, including statins and ezetimibe.

- Bempedoic acid was observed to be safe and well-tolerated. There were no differences in the occurrence of AEs, SAEs or muscle-related AEs; and no differences in discontinuations due to AEs or muscle-related AEs between the bempedoic acid group compared to the placebo group.

Phase 2 Clinical Studies Completed in 2018

1002-039 Phase 2 efficacy and safety study of bempedoic acid when added-on to an injectable proprotein convertase subtilisin/kexin type 9 inhibitor, or PCSK9i, therapy in patients with hypercholesterolemia

On March 27, 2018, we announced top-line results from the Phase 2 clinical study (1002-039) of bempedoic acid when added-on to an injectable PCSK9i therapy. The eight-week Phase 2, randomized, double-blind, placebo-controlled,

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multicenter study evaluated the efficacy and safety of once-daily, oral bempedoic acid 180 mg in patients with hypercholesterolemia at screening (LDL-C ≥ 160 mg/dL). These patients received 12 weeks of background injectable evolocumab 420 mg administered every four weeks prior to randomization. A total of 59 patients from 21 sites in the U.S. and Canada were then randomized 1:1 to receive bempedoic acid or placebo added-on to evolocumab for eight weeks. The primary efficacy objective was to assess the eight-week LDL-C lowering efficacy of bempedoic acid versus placebo in patients on a PCSK9 inhibitor. Secondary objectives included evaluating the safety and tolerability of bempedoic acid versus placebo and its effects on other risk markers, including hsCRP. While analyses of the complete efficacy and safety results from 1002-039 are ongoing, the top-line results are summarized as follows:

LDL-Cholesterol Percent Change from Baseline to Week 8 Endpoint

Treatment Group	Number of Patients	LDL-C Baseline Mean (SD) mg/dL	LDL-C Week 8 Endpoint Mean (SD) mg/dL	Percent Change from Baseline LS Mean (SE)	P Value
Bempedoic Acid + PCSK9i	27	103 (29)	74 (26)	27% (4.3)	<0.001
Placebo + PCSK9i	26	107 (34)	106 (25)	+3% (3.4)	

LS = least squares; SD = standard deviation; SE = standard error; mITT population

hsCRP Nonparametric Analysis

Treatment Group	Number of Patients	Baseline Level (mg/L)	Percent Change from Baseline Median Change	P Value
Bempedoic Acid + PCSK9i	27	3.0	34%	<0.029
Placebo + PCSK9i	25	1.9	2%	

- After eight weeks of treatment with bempedoic acid added-on to PCSK9i, the primary endpoint of the study, LDL-C levels were lowered by an additional 30% (p<0.001), with a decrease of 27% from baseline for the patients treated with bempedoic acid and an increase of 3% for patients who received placebo.

- hsCRP, a marker of inflammation associated with CVD, was reduced by 34% (p<0.029) for patients dosed with bempedoic acid added-on to PCSK9i after eight weeks of therapy, versus a 2% reduction with placebo.

- Clinically significant reductions in total cholesterol, apoB and non-HDL-C were seen in the patients treated with the bempedoic acid.

- No discontinuation occurred during the study. There were no increases (repeated and confirmed) in liver function tests.

- Bempedoic acid was observed to be safe and well-tolerated. There were essentially no differences in the occurrence of AEs, SAEs or muscle-related AEs between the bempedoic acid and placebo groups.

Ongoing Clinical Studies

1002FDC-058 Phase 2 efficacy and safety study of the bempedoic acid / ezetimibe combination pill in patients with hypercholesterolemia and Type 2 Diabetes

1002FDC-058 is a Phase 2 clinical study assessing the efficacy and safety of the bempedoic acid / ezetimibe combination pill in patients with hypercholesterolemia and type 2 diabetes. Initiated in June 2018, the 12-week, randomized, double-blind, placebo-controlled, parallel-dose study consists of three treatment arms evaluating the efficacy and safety of a once-daily, oral fixed dose combination pill of bempedoic acid 180 mg and ezetimibe 10 mg versus placebo and versus ezetimibe 10 mg alone. The study is expected to enroll approximately 168 patients at approximately 45 sites across the U.S.

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The co-primary objectives of the study are to assess the 12-week LDL-C lowering efficacy in patients treated with the bempedoic acid / ezetimibe combination pill versus placebo and versus ezetimibe 10 mg alone. Secondary objectives include evaluating 12-week hsCRP, non-HDL-C, apoB, total cholesterol and triglycerides. Exploratory objectives include 12-week HbA1c, fasting glucose, fasting insulin and additional glycemic measurements. We expect to report top-line results in the second half of 2019 and the data from this study will not be included in the NDA submissions for bempedoic acid and the bempedoic acid / ezetimibe combination pill.

Open-Label Extension of Study 1 Global pivotal Phase 3 long-term safety and tolerability study in patients with hypercholesterolemia on maximally tolerated background lipid-modifying therapy

Safety data will be obtained from an open-label extension study which completed enrollment of 1,462 of the 2,230 patients enrolled in Study 1 in March 2018. Initiated in February 2017, this open-label extension study will evaluate the long-term safety of bempedoic acid 180 mg in high CVD risk patients with hypercholesterolemia and with ASCVD and/or HeFH whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are taking maximally tolerated statin therapy. This open-label extension study will be conducted at approximately 100 sites included in the parent study in the U.S., Canada and Europe. The primary objective is to assess the long-term safety in patients treated with bempedoic acid for up to 1.5 years. Secondary objectives include evaluating the 52- and 78-week effects of bempedoic acid on lipid and cardiometabolic risk markers, including LDL-C, non-HDL-C, total cholesterol, apoB and hsCRP.

Global Cardiovascular Outcomes Trial CLEAR Outcomes

CLEAR Outcomes is an event driven, global, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid in patients with ASCVD and/or HeFH, or who are at high risk for CVD, with hypercholesterolemia and who are only able to tolerate less than the lowest approved daily starting dose of a statin and can be considered statin intolerant. The CLEAR Outcomes CVOT is expected to enroll approximately 12,600 patients with ASCVD or at high risk for CVD in over 1,000 sites in approximately 30 countries. The study is expected to enroll over a 30 month period with a total estimated study duration of approximately 4.75 years. The expected average treatment duration will be 3.75 years with a minimum treatment duration of approximately 2.25 years. Patients enrolling in the study will be required to have a history of, or be at high risk for, CVD with LDL-C levels greater than 100 mg/dL despite background lipid-lowering therapy, resulting in an expected average baseline LDL-C level in all patients of approximately 135 mg/dL. The primary efficacy endpoint of the event-driven global study is the effect of bempedoic acid versus placebo on the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or coronary revascularization; also referred to as four-component MACE). We initiated CLEAR Outcomes in December 2016, and the study is intended to support our submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. In the future, we may never generate revenue from the sale of the bempedoic acid / ezetimibe combination pill or bempedoic acid or other product candidates. If we fail to complete the development of the bempedoic acid / ezetimibe combination pill or bempedoic acid or any other product candidates and secure approval from regulatory authorities, our ability to generate future revenue and our results of operations and financial position will be adversely affected.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting nonclinical, preclinical and clinical studies. Our research and development expenses consist primarily of costs incurred in connection with the development of the bempedoic acid / ezetimibe combination pill and bempedoic acid, which include:

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical and clinical studies;

- the cost of acquiring, developing and manufacturing clinical study materials, including the procurement of ezetimibe in our continued development of our bempedoic acid / ezetimibe combination pill;

- employee-related expenses, including salaries, benefits, stock-based compensation and travel expenses;

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- allocated expenses for rent and maintenance of facilities, insurance and other supplies; and

- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. To date, substantially all of our research and development work has been related to bempedoic acid. Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies. We do not allocate acquiring and manufacturing clinical study materials, salaries, stock-based compensation, employee benefits or other indirect costs related to our research and development function to specific programs.

Our research and development expenses are expected to continue in the foreseeable future as they relate to our ongoing CLEAR Outcomes CVOT, our planned NDA and MAA submissions and any other early-stage development programs or additional indications we choose to pursue. Research and development expenses associated with our global pivotal Phase 3 LDL-C lowering program are expected to significantly decrease as we complete the program in the fourth quarter of 2018. We cannot determine with certainty the duration and completion costs associated with the ongoing or future clinical studies of the bempedoic acid / ezetimibe combination pill and bempedoic acid. Also, we cannot conclude with certainty if, or when, we will generate revenue from the commercialization and sale of the bempedoic acid / ezetimibe combination pill or bempedoic acid, if ever. We may never succeed in obtaining regulatory approval for the bempedoic acid / ezetimibe combination pill or bempedoic acid. The duration, costs and timing associated with the development and commercialization of the bempedoic acid / ezetimibe combination pill and bempedoic acid will depend on a variety of factors, including uncertainties associated with the results of our clinical studies and our ability to obtain regulatory approval. For example, if the FDA or another regulatory authority were to require us to conduct clinical studies beyond those that we currently anticipate will be required for the completion of clinical development or post-commercialization clinical studies of the bempedoic acid / ezetimibe combination pill or bempedoic acid, or if we experience significant delays in enrollment in any of our clinical studies, we could be required to expend significant additional financial resources and time on the completion of clinical development or post-commercialization clinical studies of the bempedoic acid / ezetimibe combination pill and bempedoic acid.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries and related costs for personnel, including stock-based compensation, associated with our executive, accounting and finance, operational and other administrative functions. Other general and administrative expenses include facility-related costs, communication expenses and professional fees for legal, patent prosecution, protection and review, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in the future in connection with the continued research and development and commercialization of the bempedoic acid / ezetimibe combination pill and bempedoic acid, including costs to support a commercial launch, increases in our headcount, expansion of our information technology infrastructure, and increased expenses associated with being a public company and complying with exchange listing and Securities and Exchange Commission, or SEC, requirements. These increases will likely include higher legal, compliance, accounting and investor and public relations expenses.

Other Income, Net

Other income, net, primarily relates to interest income and the accretion or amortization of premiums and discounts earned on our cash, cash equivalents and investment securities, and also includes interest expense associated with our credit facility and non-cash interest costs associated with the amortization of the related debt discount, deferred issuance costs and final payment fee.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors

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that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

In January 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-01 which includes provisions to accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. The updated guidance requires equity investments with determinable fair values to be measured at fair value with changes in fair value recognized in income. Equity investments without determinable fair values are to be measured at cost, less any impairment determined to be other than temporary. We adopted ASU 2016-01 effective January 1, 2018. Prospectively, unrealized gains or losses from equity investments with readily determinable fair values will be reflected in earnings through Other income, net on the statement of operations and any equity investments owned by us without readily determinable fair values will be measured at cost, less any impairment determined to be other than temporary. The adoption of the ASU did not have a material impact on our balance sheets, statements of operations or statements of cash flows.

In May 2017, the FASB issued ASU 2017-09 which includes provisions to clarify when to account for a change to terms or conditions of a share-based payment award as a modification. Under the updated guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. We adopted ASU 2017-09 effective January 1, 2018. The adoption of the ASU did not have a material impact on our balance sheets, statements of operations or statements of cash flows.

In August 2018, the FASB issued ASU 2018-15 which includes provisions to clarify customer s accounting for implementation costs incurred in a cloud computing arrangement. Under the updated guidance, a customer in a cloud computing arrangement that is a service contract should follow the internal-use software guidance to determine how to account for costs incurred in implementation. The updated guidance also requires certain classification on the balance sheets, statements of operations and statements of cash flows as well as additional quantitative and qualitative disclosures. The standard is effective for public companies for fiscal years beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted and entities can choose to adopt the new guidance prospectively or retrospectively. We do not believe the adoption of this standard will have a material impact on our balance sheets, statements of operations or statements of cash flows.

There have been no other material changes to the significant accounting policies previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,

	2018	2017	Change
	(unaudited, in thousands)		
Operating Expenses:			
Research and development	$ 41,551	$ 40,056	$ 1,495
General and administrative	9,011	5,681	3,330
Loss from operations	(50,562)	(45,737)	(4,825)
Other income, net	651	518	133
Net loss	$ (49,911)	$ (45,219)	$ (4,692)

Research and development expenses

Research and development expenses for the three months ended September 30, 2018, were $41.6 million, compared to $40.1 million for the three months ended September 30, 2017, an increase of $1.5 million. The increase in research and development expenses was primarily related to clinical development costs for the bempedoic acid / ezetimibe combination pill and bempedoic acid, including costs to support the completion of the pivotal Phase 3 study for the bempedoic acid / ezetimibe combination pill during the period, the ongoing CLEAR CVOT, and increases in our headcount and stock-based compensation expense.

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General and administrative expenses

General and administrative expenses for the three months ended September 30, 2018, were $9.0 million, compared to $5.7 million for the three months ended September 30, 2017, an increase of $3.3 million. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, including costs to support pre-commercialization activities, further increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Other income, net

Other income, net for the three months ended September 30, 2018, was $0.7 million, compared to $0.5 million for the three months ended September 30, 2017. This increase was primarily related to an increase in interest income earned on our cash, cash equivalents and investment securities and a reduction in expense for the amortization of premiums and discounts on our investments.

Results of Operations

Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		
	2018	2017	Change
	(unaudited, in thousands)		
Operating Expenses:			
Research and development	$ 122,015	$ 114,164	$ 7,851
General and administrative	21,921	16,122	5,799
Loss from operations	(143,936)	(130,286)	(13,650)
Other income, net	2,165	1,189	976
Net loss	$ (141,771)	$ (129,097)	$ (12,674)

Research and development expenses

Research and development expenses for the nine months ended September 30, 2018, were $122.0 million, compared to $114.2 million for the nine months ended September 30, 2017, an increase of approximately $7.8 million. The increase in research and development expenses was primarily related to clinical development costs for the bempedoic acid / ezetimibe combination pill and bempedoic acid, including costs to support the completion of three global pivotal Phase 3 studies for bempedoic acid and the pivotal Phase 3 study for the bempedoic acid / ezetimibe combination pill during the period, the ongoing CLEAR CVOT, and increases in our headcount and stock-based compensation expense.

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2018, were $21.9 million, compared to $16.1 million for the nine months ended September 30, 2017, an increase of $5.8 million. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, including costs to support pre-commercialization activities, further increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Other income, net

Other income, net for the nine months ended September 30, 2018, was $2.2 million, compared to $1.2 million for the nine months ended September 30, 2017. This increase was primarily related to an increase in interest income earned on our cash, cash equivalents and investment securities and a reduction in expense for the amortization of premiums and discounts on our investments.

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Liquidity and Capital Resources

We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock and the incurrence of indebtedness. In August 2017, we completed an underwritten public offering of 3,100,000 shares of common stock. We also granted the underwriters a 30-day option to purchase up to 465,000 additional shares of our common stock, which was exercised in full in September 2017. All of the shares were offered by us at a price to the public of $49.00 per share for net proceeds of $164.0 million. To date, we have not generated any revenue and we anticipate that we will continue to incur losses for the foreseeable future.

As of September 30, 2018, our primary sources of liquidity were our cash and cash equivalents and available-for-sale investments, which totaled $26.8 million and $137.6 million, respectively. We invest our cash equivalents and investments in highly liquid, interest-bearing investment-grade and government securities to preserve principal.

The following table summarizes the primary sources and uses of cash for the periods presented below:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Cash used in operating activities	$ (119,946)	$ (96,428)
Cash provided by (used in) investing activities	101,881	(84,252)
Cash provided by financing activities	10,352	163,539
Net decrease in cash and cash equivalents	$ (7,713)	$ (17,141)

Operating Activities

We have incurred and expect to continue to incur, significant costs in the areas of research and development, regulatory and other clinical study costs, associated with the development of the bempedoic acid / ezetimibe combination pill and bempedoic acid and our operations.

Net cash used in operating activities totaled $120.0 million and $96.4 million for the nine months ended September 30, 2018 and 2017, respectively. The primary use of our cash was to fund the development of the bempedoic acid / ezetimibe combination pill and bempedoic acid, adjusted for non-cash expenses such as stock-based compensation expense, depreciation and amortization and changes in working capital.

Investing Activities

Net cash provided by investing activities of $101.9 million for the nine months ended September 30, 2018, consisted primarily of proceeds from the sale and maturities of highly liquid, interest bearing investment-grade and government securities. Net cash used in investing activities of $84.3 million for the nine months ended September 30, 2017, consisted primarily of purchases of highly liquid, interest bearing

investment-grade and government securities.

Financing Activities

Net cash provided by financing activities of $10.4 million for the nine months ended September 30, 2018, related primarily to proceeds from exercise of our common stock options. Net cash provided by financing activities of $163.5 million for the nine months ended September 30, 2017, related primarily to the proceeds from our underwritten public offering of common stock.

Plan of Operations and Funding Requirements

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we progress through the clinical development program for the bempedoic acid / ezetimibe combination pill and bempedoic acid and prepare for NDA and MAA submissions and commercial launch activities. We estimate that current cash resources are sufficient to fund operations through the expected approvals of the bempedoic acid / ezetimibe combination pill and bempedoic acid in the first quarter of 2020. We will likely need to raise additional capital to continue to fund the further development and commercialization efforts for the bempedoic acid / ezetimibe combination pill and bempedoic acid and our operations and to complete the CLEAR Outcomes CVOT. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of the bempedoic acid / ezetimibe combination pill

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and bempedoic acid and the extent to which we may enter into collaborations with pharmaceutical partners regarding the development and commercialization of the bempedoic acid / ezetimibe combination pill and bempedoic acid, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development and commercialization of the bempedoic acid / ezetimibe combination pill and bempedoic acid. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to successfully develop and commercialize the bempedoic acid / ezetimibe combination pill and bempedoic acid or other product candidates;

- the costs, timing and outcomes of our ongoing and planned clinical studies of the bempedoic acid / ezetimibe combination pill and bempedoic acid;

- the time and cost necessary to obtain regulatory approvals for the bempedoic acid / ezetimibe combination pill and bempedoic acid, if at all;

- our ability to establish a sales, marketing and distribution infrastructure to commercialize the bempedoic acid / ezetimibe combination pill and bempedoic acid or our ability to establish any future collaboration or commercialization arrangements on favorable terms, if at all;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and

- the implementation of operational and financial information technology.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners or royalty-based financing arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements or royalty-based financing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market the bempedoic acid / ezetimibe combination pill and bempedoic acid that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

On July 6, 2018, we signed the first amendment of the lease for our principal executive office in Ann Arbor, Michigan. The amended lease is to increase the current 7,941 rentable square feet of office space by 11,471 rentable square feet. The lease has a term of 60 months and provides for fixed monthly rent of $19,412 until the end of the 12th month, with scheduled increases every 12 months, and also provides for certain rent adjustments to be paid as determined by the landlord.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

Off-Balance Sheet Arrangements

We do not currently have, nor did we have during the periods presented, any off-balance sheet arrangements as defined by Securities and Exchange Commission rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We had cash and cash equivalents and available-for-sale investments of approximately $26.8 million and $137.6 million at September 30, 2018, and $34.5 million and $239.2 million at December 31, 2017, respectively. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk relates to fluctuations in interest rates which are affected by changes in

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the general level of U.S. interest rates. Given the short-term nature of our cash and cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We do not have any foreign currency or other derivative financial instruments.

We do not believe that our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

We contract with CROs and investigational sites globally. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk. We do not believe that fluctuations in foreign currency rates have had a material effect on our results of operations during the nine months ended September 30, 2018.

Inflation generally affects us by increasing our cost of labor and clinical study costs. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2018.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2018, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

On January 12, 2016, a purported stockholder of our company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against us and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that we and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving our lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, we filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted our motion to dismiss with prejudice and entered judgment in our favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment. In May 2017, the court denied the plaintiff s motion to alter or amend the judgment. On June 19, 2017, the plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court s dismissal and remanded for further proceedings. On October 11, 2018, we filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit Court of Appeals directed plaintiffs to respond to that petition. We are unable to predict the outcome of this matter and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

On May 7, 2018, a purported stockholder of our company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, captioned *Kevin Bailey v. Esperion Therapeutics, Inc., et al. (No. 18-cv-11438*). An amended complaint was filed on October 22, 2018, against us and certain directors and officers. The amended complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 based on allegedly making false and misleading statements about the facts and circumstances surrounding the Phase 3 trial results for bempedoic acid that we announced on May 2, 2018. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between February 22, 2017, and May 22, 2018, as well as attorneys fees and costs. We are unable to predict the outcome of this matter and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

There have been no other material changes to our legal proceedings outside the ordinary course of business from those previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

Except for the historical information contained herein or incorporated by reference, this report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in the following section, as well as those discussed in Part I, Item 2 entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this report and in any documents incorporated in this report by reference.

You should consider carefully the following risk factors, together with those set forth in Part I, Item 1A in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in all of the other information included or incorporated in this report. The following risk factors represent new risk factors or those containing changes, including material changes, to the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. If any of the previously identified or following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business,

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financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to the Securities Markets and Investment in our Common Stock

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. For example, a purported securities class action lawsuit was filed in January 2016 naming us and certain of our officers as defendants. In December 2016, the federal district court granted our motion to dismiss with prejudice and entered judgment in our favor. In May 2017, the court denied plaintiffs motion to alter or amend that judgment. On June 19, 2017, plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court s dismissal and remanded for further proceedings. On October 11, 2018, we filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit Court of Appeals directed plaintiffs to respond to that petition.

Additionally, in December 2016, a purported derivative action was filed in Delaware against certain of our directors and officers. In May 2018, a purported securities class action lawsuit was filed naming us and certain of our officers as defendants.

Any lawsuit to which we or our directors or officers are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Any of these results could adversely affect our business. In addition, defending claims is costly and can impose a significant burden on our management. This proceeding and any others in which we may become involved could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 6. Exhibits

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

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EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference to: Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	S-1/A	3.2	6/12/2013	333-188595
3.2	Amended and Restated By-Laws of the Registrant.	S-1/A	3.4	6/12/2013	333-188595
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	4.1	6/12/2013	333-188595
10.1	First Amendment to Valley Ranch Business Park Lease, dated July 6, 2018, between the Registrant and Blackbird Ann Arbor, LLC.	10-Q	10.1	8/2/2018	001-35986
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Document.				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.				

101.PRE*	XBRL Taxonomy Extension Presentation Link Document.

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* Filed herewith.

+ The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ESPERION THERAPEUTICS, INC.

November 1, 2018 By: /s/ Tim M. Mayleben
Tim M. Mayleben
President and Chief Executive Officer
(Principal Executive Officer)

November 1, 2018 By: /s/ Richard B. Bartram
Richard B. Bartram
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)